REMARKS

This amendment under 37 CFR 1.116 after final rejection because Applicants believe that all claims now presented are in condition for allowance. In any event entry of this amendment will place the application in better form for prosecution before the US Patent and Trademark Office. Applicants have added no new matter and raised no new issues. Finally the changes in the claims and arguments presented herein are in direct response to points raised by the Examiner in the last office action and applicants could not have made this response at an earlier date.

Applicants wish to thank Examiner Mahyers and Examiner Woodward for conducting a telephone interview with the Applicants' undersigned attorney on 20 August 2008. The Examiners and the undersigned discussed the definition of "a therapeutically effective amount" of alginic acid or sodium alginate. The undersigned referred the Examiners to EP 0 059 221 cited in the background portion of the present application in the paragraph bridging pp 2 and 3 and pointed out that this reference discloses the cytoprotective effective of alginic acid/sodium alginate in the gastrointestinal tract. Pages 7 and 8 of the European Patent disclose that the concentration of alginic acid/sodium alginate may range between 2W/V% and 5W/V% and that the dose of the alginic acid/sodium alginate composition ranges between 10 and 100 ml. The undersigned then emphasized that there is no disclosure or

suggestion in the reference to administer the alginic acid/sodium alginate together with alendronate sodium coated with a polymer that is insoluble in the upper gastrointestinal tract, but soluble at the acid pH of the stomach, but that the same amount of alginic acid./sodium alginate as applied in the European Patent may be applied here as well.

The undersigned also pointed out that there is an example in the present application of a composition that contains both the coated alendronate sodium and the alginic acid/sodium alginate and so Applicants strongly believe that one "skilled in the art" having the present application with the working example and EP 0 059 221 would clearly understand what is meant by a therapeutically effective amount of the alginic acid/sodium alginate. Thus the Examiners should no longer maintain rejection of any claim under 35 USC 112, second paragraph, as indefinite.

The Examiners indicated that they agreed with these arguments and that as a result they would be inclined to remove the rejection of the claims under 35 USC 112, second paragraph as indefinite.

The undersigned then turned to the prior art references cited in combination, namely CLANCY et al and PATEL et al. Applicants emphasized that the CLANCY et al reference is directed to alendronate sodium that is coated with an enteric coating so that the alendronate sodium is not released from the coating until

the composition reaches the intestines. The Applicant's present invention is significantly different because it is released from the coating in the stomach, not the intestines. Furthermore the CLANCY et al compositions do not include alginic acid/sodium alginate as a second important ingredient. The undersigned then directed comments to the PATEL et al reference which discloses in Example 14 a composition which contains alginic acid/sodium alginate and alendronate sodium. Example 14 makes no mention one way or the other about coating. However, Applicants emphasized that col. 42 of PATEL et al discloses that the pharmaceutical compositions therein may be coated with one or more of the following: (1) a seal coating with or without an isolation layer, (2) an extended release coating or (3) an enteric coating. The enteric coating is similar to what is disclosed in CLANCY et al, except that the PATEL et al composition also included alginic acid/sodium alginate. However, when PATEL et al coats its pharmaceutical compositions with a seal coating that could include EUDRAGIT E, a coating that breaks up in the stomach, the seal coating is over the entire composition, that is over not only the alendronate sodium, but over the alginic acid/sodium alginate as well. Thus the alginic acid sodium alginate will not be available to treat the upper gastrointestinal tract because it is sealed off with the coating and not released until the medication reaches the stomach.

The undersigned pointed out that the purpose of using the alginic acid/sodium alginate according to PATEL et al is to provide a buffer (see col. 49, line 47) and the purpose of the EUDRAGIT E 100 is to hide the unpleasant taste of the medication from the patient. See col. 42, lines 30 to 42. Each of these purposes is completely different from the purposes of those ingredients according to the present invention.

Examiner Woodward suggested that in order to better distinguish over the combination of cited references, particularly PATEL et al, Applicants should amend the proposed claims to state that the alginic acid or sodium alginate is uncoated. He indicated that such an amendment would appear to distinguish over the cited combination of prior art references.

Lastly the undersigned discussed with the Examiners the rejection of claim 10 under 35 USC 112, first paragraph, as unsupported by the disclosure because of the term "consisting essentially of". Examiner Woodward stated that Applicants can change "consisting essentially of" to "consisting of" if they wish, but that he believed that Applicants should return to "comprises" which is broader and gives Applicants more protection.

Applicants have accordingly amended claims 1, 7, 9 and 10 in accordance with the suggestions of the Examining Attorney.

Applicants believe that all claims now presented are in condition for allowance and a response to that effect is earnestly solicited.

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